

Clinical Trial Update

Open Study Examines Partial Breast Irradiation for Early-Stage Breast Cancer

Study Objective

The National Surgical Adjuvant Breast and Bowel Project (NSABP) and the Radiation Therapy Oncology Group (RTOG) have launched a Phase III clinical trial to determine whether limiting radiation therapy to only the tumor site following lumpectomy, a procedure known as partial breast irradiation or PBI, provides equivalent local tumor control and survival compared to conventional whole breast irradiation (WBI) in the local management of early-stage breast cancer.

It is important to determine whether PBI works as well as WBI before it becomes an alternative to WBI. The trial, known as NSABP B-39/RTOG 0413, will involve 3,000 women from North America at approximately 150 study sites. The NSABP and the RTOG are clinical trials cooperative groups funded primarily by the National Cancer Institute. Both groups have conducted decades of research with results that have changed the way cancer is treated.

Study Background

Whole breast irradiation has been proven to be effective in combination with lumpectomy in the treatment of breast cancer and has been shown to decrease disease recurrence. Standard therapy after a tumor is surgically removed generally includes six weeks of external beam radiation therapy (RT) to the whole breast followed by a boost to the tumor bed (lumpectomy site). External beam radiation therapy is radiation therapy that uses a machine to aim high-energy rays at the cancer. WBI is used in an attempt to control cancer cells that may be left behind after surgery alone and thus reduces the risk of tumor recurrence in the breast.

The biological significance of these microscopic cancer cells is unknown, and the necessity to treat the entire breast to prevent cancer recurrence has been questioned. In at least five clinical trials, the outcomes of patients treated with excisional biopsy alone or followed by WBI have been studied. The majority of recurrences in the breasts of patients who did receive RT occurred at or in the area of the tumor bed. Data from recent studies suggest that an accelerated course of RT delivered over four to five days and restricted to the tumor bed may be as effective as WBI.

Recent developments in PBI have resulted in several comparable and reproducible techniques that are safe and tolerable. In addition to readily available 3D external beam technology, “user friendly” interstitial breast brachytherapy techniques have been developed. Brachytherapy is a procedure in which sealed radioactive material (small pellets) is placed directly into or near the prior tumor site and removed after treatment. This includes multicatheter techniques and more recently the Mammosite™ single catheter technique, which is more easily taught and performed and more comfortable for patients. These developments have increased interest in PBI as a treatment option.

Twenty-year results from NSABP Protocol B-06 continue to show that lumpectomy plus radiation therapy is equivalent to mastectomy. Even when appropriate, some women may opt for a mastectomy because radiation therapy must be given five days a week over five to seven weeks. If PBI is as effective as WBI, this may allow more women with breast cancer to select the less disfiguring procedure, lumpectomy.

Study Design

The NSABP B-39/RTOG 0413 trial will enroll women with early-stage breast cancer (stage 0, I or II) whose tumor size is 3.0 cm or smaller. All patients will have a lumpectomy and then be randomly assigned to either receive WBI or PBI. Women assigned to the WBI group will receive RT daily on five days a week for five to seven weeks. Those assigned to the PBI group will receive RT twice a day on five days over a one- to two-week period. Patients may receive chemotherapy or hormonal therapy at the discretion of their doctors.

This trial also has a unique Quality of Life component that will evaluate the cosmetic results of both PBI and WBI, as well as the effect on fatigue, treatment-related symptoms and participants' perceived convenience of care. The quality-of-life and cosmesis evaluations will involve 482 enrolled participants who intend to receive chemotherapy and 482 enrolled patients who intend not to receive chemotherapy. Cosmetic outcomes will be evaluated by patient self-reports and by the radiation oncologist using validated criteria.

Lastly, digital images will be taken of the patient's treated and untreated breasts. The images will not identify the person. These images will be taken at study entry, at one year and at three years. The images will be evaluated by a panel of physicians using established criteria. Among the outcomes to be studied are degree of scarring, the extent of pockmarks and/or dimpling, degree of symmetry between the breasts and the extent of changes to the skin.

For More Information

For more information and to locate a participating site in the United States, please call the National Cancer Institutes Cancer Information Service at 1.800.4.CANCER (1.800.422.6237).

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